Recommendations for Addressing Perinatal Hepatitis C (HCV) in San Francisco

Final Report

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Background

Hepatitis C virus (HCV) is the most frequently reported bloodborne infection in the United States, with an estimated 57,500 new infections since 2018.[1] Over 60% of new HCV infections reported to the Centers for Disease Control and Prevention (CDC) in 2018 were among persons aged 20–39 years old,[2] with perinatal transmission on the rise as a result of this demographic shift toward people of childbearing age. In 2017, 0.4% of live births in the United States were delivered by women with HCV infection, with an estimated 6% of infants born to women living with hepatitis C becoming chronically infected.[3]

As the number of acute and chronic cases of HCV continues to rise, governing U.S. public health organizations have recommended an increase in screening. The United States Preventive Services Task Force (USPSTF) now recommends that all adults be screened once in their lifetime, regardless of specific risk.[4] Due to the increase in infections among women of childbearing age and the implications for perinatal transmission, the CDC recently revised their HCV screening recommendations to include screening for pregnant individuals during each pregnancy, in addition to screening for all adults at least once in their lifetime.[5] Similarly, the American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD-IDSA) recommends screening all pregnant people for HCV, ideally at the initial prenatal care visit.[6] The American College of Obstetricians and Gynecologists has also updated its screening guidance to recommend screening for all pregnant individuals during each pregnancy.[7] These new recommendations are largely in response to the alarming increase in prevalence of chronic HCV infections in 20- to 39-year-olds, thought to be driven at least in part by needle-sharing in the ongoing opioid epidemic.[8]

Ultimately, for San Francisco to thoroughly address and prevent perinatal HCV transmission, it requires attention to two groups: people living with HCV who are pregnant, and people living with HCV who could become pregnant. The former group is a smaller, more easily defined group of people who are more likely than others to be engaged in medical care, or at least to be identified as out of care and readily linked to prenatal services. However, there is currently no FDA-approved HCV treatment for use during pregnancy, and thus screening during pregnancy is too late for primary prevention of perinatal transmission. Instead, obstetrician-gynecologists (OB-GYNs) are encouraged to link pregnant patients who test positive for HCV during pregnancy to hepatology care so that they may begin direct-acting antiviral treatment (DAAs) postpartum, or after breastfeeding is complete. Babies born to people living with HCV should be tested for HCV RNA within 18 months of birth, and if HCV infection is detected they should be re-tested and treated at age 3, at which age DAAs are approved for use.[6]

Ideally, HCV infection should be diagnosed among people with the capacity to become pregnant *before* pregnancy; when possible, pre-pregnancy screening is recommended in individuals who have not yet been screened, in accordance with the recommendation for screening at least once in all adults.[5] When people are diagnosed with HCV infection before pregnancy, they should be connected with care so that they can explore completing DAA treatment before becoming pregnant. However, while this group is the most ideal to focus on to prevent perinatal HCV transmission, it is a very large and not-easily-defined group of people. It is also necessary to include people with the capacity to become pregnant who are not cisgender women (i.e., trans men and some non-binary people can also become pregnant), further expanding the breadth of programming needed to reach such a diverse group.

In 2020, the CDC's Division of Viral Hepatitis prioritized decreasing perinatal viral hepatitis infections nationally in its 2020-2025 Strategic Plan.[9] In San Francisco, *End Hep C SF* prioritized the identification of service gaps in perinatal HCV to be covered during 2020-2022, per their most recent strategic plan.[10] San

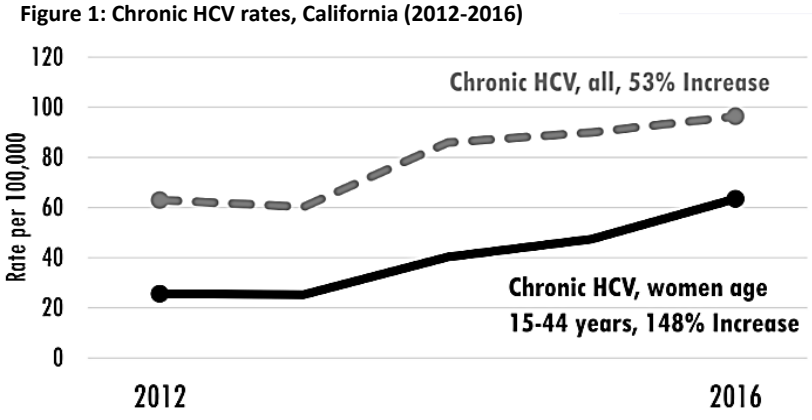
Francisco has had incredible successes preventing perinatal HIV transmission (with zero cases since 2005),[11] maintains a strong perinatal hepatitis B (HBV) program,[12] and recently has increased its focus on congenital syphilis prevention.[13] The San Francisco Department of Public Health (SFDPH) has an opportunity to take the lessons learned from these successes and apply them to perinatal HCV. Other health departments in the United States have models for this work that have yielded impressive results, proving that perinatal HCV is indeed preventable, with the right resources and attention allocated to the effort. With that in mind, this report aims to summarize various prevention and monitoring opportunities and service gaps in addressing the burden of perinatal HCV in San Francisco, serving as a foundation for a citywide strategy to eliminate perinatal HCV.

Epidemiology of Perinatal Hepatitis C in San Francisco

In addition to the markedly increasing rates of HCV infection among women between ages 20-39 in the United States,[2] there has specifically been an increase in the rate of HCV infection reported in people diagnosed during pregnancy, exceeding what is reported for both HBV and HIV infections diagnosed during pregnancy in the U.S. as of 2011.[14]

According to data from the National Notifiable Diseases Surveillance System, of 425,322 cisgender women with confirmed HCV infection in the United States from 2006 to 2014, 171,801 (40.4%) were of reproductive age.[15] During that same time, the number of *newly reported* HCV cases among this population nearly doubled, from 15,500 in 2006 to 31,039 in 2014, and the proportion of infants born to people living with HCV increased 68% nationally.[15] Kentucky holds the distinction of being the state with the highest incidence of HCV during the period 2011-2014, with the proportion of infants born to cisgender women living with HCV increasing by more than 200% during that period.[16] Kentucky responded by mandating universal HCV screening for all pregnant people in 2018, and found great improvements in diagnosis rates, leading to improved perinatal care.[17] In California, rates of chronic HCV among cisgender women of childbearing age increased more than 140% during that period (see Figure 1)[18] – following Kentucky relatively closely and far above the national average of 68%, though no similar actions mandating universal screening of pregnant women have yet been taken in California or San Francisco. (It is worth noting that data on people who can become pregnant but are not cisgender women are lacking in California and throughout the U.S.; the lack of data on this group is not an excuse to exclude them from interventions to address perinatal HCV, and strides must be made to improve data collection to bring clarity to this issue.)

Figure 1: Chronic HCV rates, California (2012-2016)



In 2021, *End Hep C SF* released an updated estimate of the number of people living with HCV in the city as of 2019, and specifically estimated the prevalence of vertical transmissions likely occurring that year,[19] though no empirical data exist to document these findings. According to this analysis, there were 45.8 live births per 1,000 women aged 15-44 in San Francisco in 2017 (the last year for which birth data

is publicly available),[20] and **there were an estimated 2,371 (95% CI: 1,253 – 5,966) cisgender women with the capacity to become pregnant who were living with chronic HCV infection in San Francisco.** This equates to an estimated 109 births (95% CI: 57 – 273) to cisgender women living with HCV that year; assuming a risk of vertical transmission of approximately 4% (95% CI: 1.0 – 7.1%),[21,22] this suggests that **there were likely an estimated 4 infants (plausible range: 1 – 19) born with HCV infection in San Francisco in 2019**. However, no perinatal HCV infections were identified and reported to the health department, as would be legally required upon diagnosis.

While there were no cases of infants born with HCV reported to the health department, **there were 447 cases of HCV infection reported to SFDPH in 2019 among women of childbearing age (defined as age 15-50), with 198 newly reported HCV cases in this group (suggesting initial diagnosis in 2019).**[23] The vast majority of these newly reported cases were from the San Francisco Health Network (Zuckerberg San Francisco General or Community Health Network clinics, n = 59, 29.8% of newly reported HCV cases), with the remaining largely coming from Kaiser Permanente (n = 28, 14.1%), UCSF (n = 20, 10.1%), and Sutter Health (n = 16, 8.1%). The remaining 49 cases with known ordering facilities were spread among 31 sites throughout the city, ranging from dialysis centers to fertility clinics to methadone clinics to private physicians.

Taken together, these local data points highlight the fact that perinatal HCV infection is likely occurring in San Francisco, though it is not currently being systematically discussed, diagnosed, or reported. Particularly if the goal is to prevent vertical transmissions in the first place (as opposed to identifying babies already living with HCV and providing them with curative treatment), considerable shifts in attention and resources will be needed, since approximately 200 people of childbearing age are being newly diagnosed with HCV infection each year in San Francisco. Attending to perinatal HCV infection is also likely to improve perinatal outcomes overall in the city, as pregnant people living with HCV have high incidence of intrahepatic cholestasis of pregnancy (associated with increased rate of adverse maternal and fetal outcomes),[24] and those who already have cirrhosis are at increased risk of preeclampsia, cesarean section, hemorrhagic complication, preterm delivery, low birth weight, and both maternal and neonatal death.[25,26]

Methods for this Report

Recommendations found in this report were developed as a result of two phases of interviews. First, program managers and epidemiologists in New York City and Philadelphia were interviewed, to build a real-world understanding of how health departments in similar cities have approached perinatal HCV.

In the second phase, interviews were conducted with 21 subject matter experts in the city of San Francisco:

- **Amy Nishimura** – Epidemiologist, Viral Hepatitis Surveillance Unit, Department of Public Health (DPH)
- **Melissa Ongpin** – Epidemiologist, Communicable Disease Control Unit, DPH
- **Julie Stoltey** – (former) Director, Disease Prevention and Control, DPH
- **Rachel Grinstein** – Hepatitis C Data and Grants Coordinator, DPH
- **Ligia Afu-Li** – Coordinator, Perinatal Hepatitis B Program, DPH
- **David English** – Lead, eConsult HCV Provider; MD, Southeast Health Center, SFDPH
- **Hali Hammer** – Director, Ambulatory Care, San Francisco Health Network, DPH
- **Annie Luetkemeyer** – Infectious Disease Physician, Zuckerberg San Francisco General Hospital (ZSFG)
- **Jessica Naugle** – Nurse Practitioner, Street Medicine, DPH
- **Alyson Decker** – Nurse Practitioner, Congenital Syphilis Lead, LINCS, DPH
- **Deborah Cohan** – Medical Director, HIVE, ZSFG
- **Becca Schwartz** - Clinical Social Worker, HIVE, ZSFG

- **Jessica Shost** – Pharmacist and HCV Data Lead, San Francisco Health Plan
- **Marion Pellegrini** – Nurse Practitioner, Magnet/Strut, San Francisco AIDS Foundation
- **Julia Klems** – Hepatitis C Care Coordinator, HealthRIGHT 360
- **Tommy Le** – Management Assistant, Department of Homelessness and Supporting Housing (HSH)
- **Le'Shenna Sirles** – Family Shelter & Transitional Housing Manager, HSH
- **Janay Washington** – Adult Shelter Systems and Navigation Center Program Specialist, HSH
- **Holly Hsu** – Homeless Prenatal Program Manager, Jelani House
- **Monica Steptoe** – Director, Jelani House

Findings from these interviews – and the resulting recommendations – are detailed in the remainder of this report.

Models of Perinatal HCV Programming in Other Cities and States

Philadelphia Department of Public Health

The origin of the Philadelphia Department of Public Health (PDPH) perinatal HCV program can be traced back to 2014, when PDPH determined the number and proportion of infants being testing for HCV, the number of HCV positive infants, the number of untested infants and the estimated number of unidentified infants living with HCV in Philadelphia during 2011-2013[27] using the following data sources:

- Birth records;
- PDPH HCV case registry;
- PDPH immunization registry;
- Negative HCV test data reported to the health department; and
- Hospital medical records.

In this analysis, PDPH established that 1% of infants in Philadelphia were born to women living with HCV, but only 15% of these infants were tested for HCV per CDC guidelines. The majority of the perinatally exposed infants who became chronically HCV-infected were not identified by pediatric providers, and therefore had not yet received recommended care. As a result of the initial 2014 study and its startling testing results, PDPH launched a perinatal hepatitis C program in January 2016, and took action to improve the identification of pregnant women living with HCV and their children through the following activities:

- Notifying women living with HCV who had children aged 18-24 months, to urge them to request HCV testing at their child's 2 year well visit.
- Offering in-service training on perinatal HCV transmission, local epidemiology, and screening guidelines at Philadelphia obstetric and pediatric practices, and birth hospitals.
- Educating prenatal care providers about the urgency to screen all pregnant people for HCV.
- Providing resources for pediatric and obstetric providers about HCV, including lists of local pediatric specialists, educational posters, and screenings for under-insured children.
- Contacting pregnant people living with HCV to assess their knowledge of perinatal transmission, encourage them to seek care, and request permission to coordinate post-natal follow up between their prenatal provider and pediatricians (if the child is in their care).
- Requiring that pregnancy in a person living with HCV be reported to the PDPH, per a Board of Health regulation that passed in July 2017.[28]

Philadelphia's perinatal HCV program is run by two staff members: An epidemiologist identifies woman-infant pairs, handles program data analysis overall, and is responsible for high-level program management; A full-time project coordinator handles provider education and case management for woman-infant pairs identified through the program. No additional programmatic costs are required.

According to Danico Kuncio, who led the 2014 study, since establishing the perinatal HCV program, at least 20% of providers contacted changed the testing practices within their facility after working with the program, and more than 40% of infants born in Philadelphia had been tested for HCV per infant testing protocols in 2019, an increase of at least 25% from PDPH's 2014 analysis.

New York City Department of Health and Mental Hygiene (DOHMH)

New York City (NYC) DOHMH's perinatal work is funded under a grant from the CDC Epidemiology Laboratory Capacity Project, to match people on both the HCV case registry and birth registry, and contact postpartum women for linkage to care and HCV testing of their infants beginning in 2019. NYC is also conducting surveillance for children reported with a positive hepatitis C test result, applying the Council for State and Territorial Epidemiologists (CSTE) perinatal hepatitis C case definition for case reporting:

- an infant under 36 months of age with an HCV RNA test, a positive HCV antigen test, or other evidence of HCV viremia (e.g., genotype testing); or
- an infant between 18-36 months of age with a positive HCV antibody test result and no negative RNA, antigen, or genotype results available.[29]

Additional screening and monitoring practices currently being undertaken in NYC include:

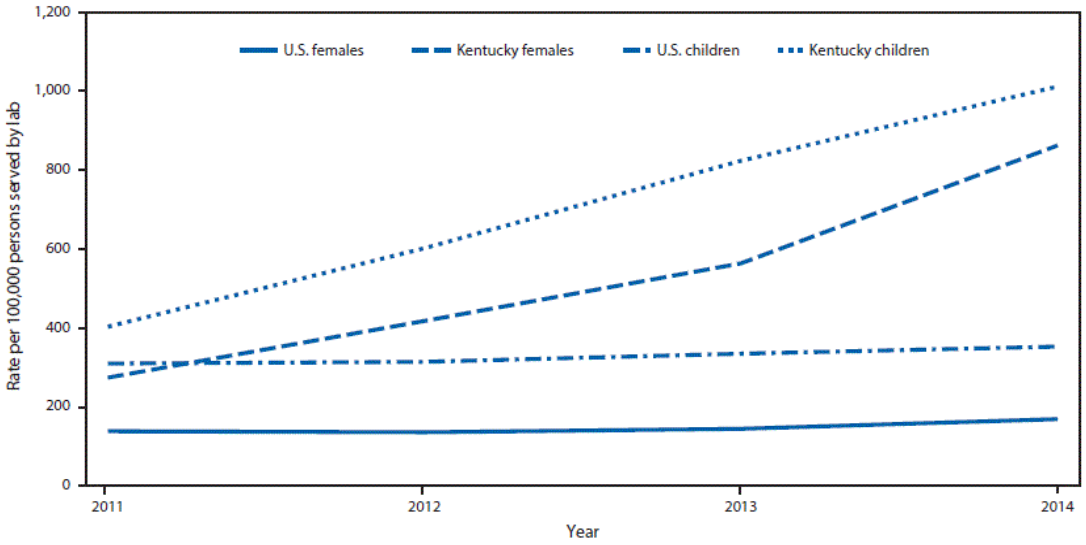
- Conducting surveillance-based telephone outreach and linkage to care to women living with HCV who have given birth.
- Recently launching perinatal hep C training workshops for clinical providers, through a partnership with the Empire Liver Foundation.[30]
- Recently updating a Dear Colleague letter reminding providers of the national recommendations for testing pregnant women and their infants for HCV.[31]

According to NYC DOHMH staff during an interview for this report, NYC has not experienced an increase in perinatal HCV transmission rates as seen in many other parts of the country. However, the health department is committed to a combination of provider education and linkage to care activities, to which they attribute the below-average prevalence of perinatal HCV infection.

Kentucky Department for Public Health

As stated earlier, Kentucky has historically had a very high incidence of HCV infection (see Figure 2[16]), and in 2015 Kentucky had an acute HCV infection rate of 2.7 per 100,000, more than 3 times the national average.[32] Many of these cases have been concentrated particularly among people aged 20-29 years, raising concerns about perinatal HCV transmission in the state. As a result, the Kentucky Viral Hepatitis Prevention Program requested in 2013 that healthcare providers voluntarily report pregnancy among people living with HCV, infants born to people living with HCV, and any children aged 0 to 5 diagnosed with HCV infection. In February 2015, this reporting was mandated by law.

Figure 2: New Diagnoses of HCV among females aged 15-44 years and children 2 years and below, US and Kentucky, 2011-2014.



From December 2013 through December 2016, 1,890 women who were pregnant or had recently given birth were reported through this system. 1,500 of those were HCV antibody positive, and of those 16.2% (243 women) had positive RNA, indicating active HCV infection. (Notably, 1,195 people, or 80% of those reported, had no confirmatory RNA test results.) Another 75 women had positive HCV RNA results reported, without a positive antibody test. In the end, the program determined that 318 people with potential perinatal HCV cases had been reported to the health department over that 3-year period; however, reports from the Office of Vital Statistics showed that 2,997 of the births in Kentucky during that time period had evidence of maternal HCV infection recorded on the birth certificate – a dramatic difference.[32]

Partially as a result of these findings, in May 2017, the Kentucky Viral Hepatitis Prevention Program decided to ramp up harm reduction efforts, adding 5 additional syringe services programs and bringing the total number of sites to 47.[33] In 2018, Kentucky legislatively mandated universal HCV screening for all pregnant women. Statewide, the prevalence of prenatal HCV screening increased from 18% before universal HCV screening was mandated in 2018 to 31% by 2020.[17] As one case study, to best comply with the new legislation, the University of Louisville Hospital implemented a program where the electronic medical record prompted ordering HCV screening labs once providers opened the admission order set for any pregnant people in delivery, unless they had been tested during the last trimester of their pregnancy or already had a known HCV diagnosis on record. The HCV screening labs included automatic reflex testing of HCV RNA for anyone found to have HCV antibodies. If the pregnant patient was found to be HCV antibody positive and RNA negative, the patient navigator was called in to provide education to the patient on past exposure to HCV and risk of re-infection. However, if the pregnant patient was found to be living with HCV, the navigator would provide patient education, link siblings to testing and care, report the case to the health department, and follow up with the mother and baby after birth to ensure treatment of the adult and testing of the baby per CDC guidelines, with treatment provided at age 3 if indicated. These initiatives resulted in a dramatic increase in detection of perinatal HCV, with 225 mothers diagnosed in that hospital by 2016, leading to PCR testing of 209 infants and detection of HCV infection for 8 infants then linked to care.[33]

The month before universal HCV screening of pregnant women become law in Kentucky, the state's Medicaid program eliminated fibrosis, sobriety, and drug-testing requirements as preconditions for receiving HCV medications. With access to treatment improving, the Kentucky Rural Health Association and University of Louisville created the Kentucky Hepatitis Academic Mentorship Program (KHAMP), a training program designed to increase the number of HCV treatment providers in high-burden, low-resource areas.

The KHAMP curriculum includes an initial in-person training session, focused on seven components:

1. HCV virology
2. HCV epidemiology with a focus on the relationship of HCV transmission to injection drug use
3. Recommended HCV testing, care, and treatment
4. HCV among pregnant women and children
5. Assessment of liver disease and fibrosis staging
6. Introduction to treatment and specialty pharmacies (both academic and commercial)
7. An overview of HCV treatments for persons who inject drugs

After several months of experience post-training, participants receive a second day of a KHAMP curriculum with four additional components:

1. Additional training in management of HCV and other liver diseases
2. Harm reduction (safe injection practices and drug treatment access)
3. Naloxone training and overdose response
4. Drug-drug interaction avoidance strategies

In addition to these two in-person sessions, all KHAMP participants are expected to participate in bimonthly webinars for a year, and have ongoing access to consultation with KHAMP faculty to support prior authorization and other medication-related activities. In two years, more than 190 participants were trained throughout the state, resulting in more than 900 consultations for treatment from people who had *never* treated a patient for HCV before KHAMP training, and more than 68 people known to be cured (with many more likely cured; consultation outcome reports are missing on more than 3/4 of cases).[34]

Kentucky represents a success story of a health department recognizing a severe HCV epidemic, particularly among people who were pregnant or of childbearing age, and made numerous structural changes to address the issue from all angles – screening, treatment, and data/reporting.

Findings and Recommendations for Perinatal HCV in San Francisco

One of the main takeaways from the many interviews conducted for this assessment with San Francisco stakeholders was that San Francisco already has the infrastructure to address perinatal HCV, but has not yet established a coordinated, citywide focus. In multiple instances, an interviewee suggested further developing or leveraging a structure that already existed (e.g., creating an HCV case registry for the San Francisco Health Network, or SFHN). Ultimately the pieces are here, but they must be woven together, with someone at SFDPH assuming responsibility for coordinating the citywide program and prompting ongoing dialogue across domains in response to the issue.

Five themes arose during this assessment, resulting in eleven recommendations, detailed below and summarized again for simplicity at the end of this report.

Theme 1: Most community providers have limited awareness of issues related to perinatal HCV

San Francisco has a strong and nationally-recognized HCV elimination initiative, *End Hep C SF*. This was the first city-based initiative in the country, and as of 2021 had more than 190 individuals participating in the collective impact initiative across 37 organizations. Within the Prevention, Testing, and Linkage workgroup, there are a number of community organizations that have demonstrated real leadership in the HCV testing arena. Staff at these programs regularly diagnose new infections and navigate people to curative treatment – particularly people who have risk factors for perinatal HCV, including people who inject drugs, are unhoused or marginally housed, or otherwise not well-engaged in the medical care system. However, each of the community organizations approached for this assessment either agreed to the interview but generally said this wasn't an area where they had much familiarity or focus, or declined to be interviewed altogether because they had "no experience with pregnant women or women of childbearing age that had HCV or were at-risk of becoming HCV," in the words of one. Representatives of the Department of Homelessness and Supportive Housing (HSH) and the Homeless Outreach Team similarly did not see perinatal HCV as something that involved them, since they "don't deal with any medical issues" (instead referring to the SFDPH Street Medicine team), and pregnant women are referred automatically to the Family Shelter System, where medical screening occurs.

In general, community providers who are building connections with people at elevated risk of becoming pregnant while living with HCV can be an incredible resource for education and linkage to screening and care. Importantly, perinatal HCV is not the only communicable disease to be addressed among pregnant people – those at increased risk of having perinatal HCV infection are also at elevated risk of having perinatal HBV infection, or giving birth to infants with HIV infection or congenital syphilis.

RECOMMENDATION 1: **For San Francisco to cohesively address perinatal HCV (ideally alongside perinatal HBV, HIV, and congenital syphilis), SFDPH should employ a multifaceted approach. Community providers who already do work related to HCV (or work with people at high risk for perinatal HCV infection) should be brought into conversations about the city's efforts to eliminate perinatal transmission of all these diseases, to determine ways they can be involved in these efforts.**

Theme 2: Improving screening and care for pregnant people with HCV is highest priority

High priority for addressing perinatal HCV is improving screening and timely linkage to care among pregnant people in San Francisco. In April 2020, while the medical world was inundated with the early stages of the COVID-19 pandemic, the US Prevention and Screening Task Force (USPSTF) and CDC released new guidance recommending **HCV screening for all pregnant women during each pregnancy**, except in settings where the prevalence of HCV infection is less than 0.1%[5] (in San Francisco the prevalence of people living with active HCV infection as of 2019 is approximately 1.3% of the total population, more than 10 times this threshold).[19]

While there are no data available to easily answer the question of how many pregnant people in San Francisco are currently being screened for HCV infection during pregnancy, anecdotally the clinicians

interviewed for this assessment universally said they did not believe HCV screening rates of pregnant people were very high. Ligia Afu-Li noted that HBV screening during pregnancy is mandated by law and the HBV screening rates are generally high, unlike with HCV (which could easily be included in the same screening panel). This may be an opportunity for *End Hep C SF* or other community partners able to work with the California Department of Public Health to advocate to change the state regulations similar to that done in Kentucky;[17] alternatively, San Francisco could decide to change local health regulations to mandate screening by order of the Local Health Officer. At a minimum, the revised USPSTF and CDC guidelines should be heavily promoted to providers of prenatal care in San Francisco, similar to NYC actions in the past 18 months.[31]

In addition to promoting this new information through a Dear Colleague letter or Health Advisory, other more informal and ongoing methods of provider education were also recommended by stakeholders. One option is to work closely with Ligia Afu-Li to outreach to prenatal providers in her network, encouraging HCV screening in conjunction with existing HBV reminders and support, and/or replicate her strategy for outreach. Hali Hammer also suggested two other important mechanisms for this type of education:

1) Coordinating with the Perinatal Linkage Group to release local guidelines on HCV screening for pregnant people, and/or other issues having to do with perinatal HCV. An easy first step could be reaching out to Liliana Ocegueda, the Perinatal Services Coordinator of SFDPH, and Angie Miller, the perinatal lead for primary care providers in the SFHN. Liliana and Angie co-facilitate the Perinatal Linkage Group.

2) Work with Dr. Joseph Pace, the Chief Medical Officer for Primary Care in the SFHN, to organize a presentation about perinatal HCV at an upcoming quarterly provider gathering. These quarterly events include 2 hours of CME, and are very popular among primary care providers in the SFHN. Dr. Hammer recommended inviting someone from the Liver Clinic at Zuckerberg San Francisco General Hospital (ZSFG) to present jointly with a primary care HCV specialist, providing information for providers about the updated HCV screening recommendations, referral guidelines, and then treatment – for HCV overall, with some focus on perinatal HCV.

RECOMMENDATION 2: **Issue a Dear Colleague letter or Health Advisory reminding clinical providers in San Francisco (including at community-based organizations offering HCV testing) about the updated CDC HCV screening recommendations for pregnant people; take other concrete steps to increase provider education on this issue in collaboration with the SFHN Perinatal Linkage Group (e.g., a presentation at an upcoming quarterly provider gathering for primary care providers in the SFHN).**

End Hep C SF partners could be an excellent collaborator in these efforts, potentially coordinating provider trainings or supporting the provision of CEUs. *End Hep C SF* clinical providers would likely also support co-authoring an advisory if needed.

Another opportunity for structural change that would greatly increase HCV screening rates in pregnancy would be to add HCV to routine screening labs for pregnant people in the SFHN, including ZSFG. The University of Louisville Hospital already demonstrated the positive impact that could have,[33] and given the updated CDC guidelines, Hali Hammer recommended this shift be made within the SFHN, potentially with the support of the Perinatal Linkage Group. David English noted that the SFHN was currently working on an EMR prompt within Epic regarding the guidelines for lifetime HCV screening for all adults,

and that this may be an opportunity to enhance that prompt with extra emphasis for people who are pregnant or planning to conceive.

RECOMMENDATION 3: **Add HCV to the routine screening labs for all pregnant people in the SFHN, including Zuckerberg San Francisco General Hospital; related, implement Epic EMR prompts to remind providers about guidelines for lifetime HCV screening, with extra emphasis on testing for people who are pregnant or pre-conception.**

In addition to provider education and prompts to encourage HCV screening during provision of prenatal care, there is also an opportunity for SFDPH to encourage community-based organizations that offer HCV testing to automatically offer HCV screening to any clients who are pregnant or desiring to become pregnant, regardless of other stated risk factors for HCV infection.

Another opportunity to improve data around perinatal HCV is to improve the pregnancy data on lab reports sent to the SFDPH under mandated or voluntary reporting. On August 27, 2019, the California Department of Public Health issued a Dear Colleague letter notifying health departments of updates to the California Code of Regulations (CCR) Title 17 § 2500 and 2505.[35] As of October 1 of that year, pregnancy status (if known) is now required to be reported on all lab reports per §2500, and all test requisitions must now include pregnancy status per §2505. Yet according to Melissa Ongpin, pregnancy data continues to be very poor on lab reports received by SFDPH, complicating the Department's ability to track potential cases of perinatal HCV and follow up with parents or infants accordingly. Ligia Afu-Li similarly noted:

> *To identify the pregnant women who are HBV-infected, Amy Nishimura sends the list of HBV-positive women of child-bearing age monthly. This can be about 75 women a month – after screening out non-SF residents, who are not eligible for the program. Then I have to screen out which ones are pregnant. We send questionnaires to the docs, but they don't respond right away. In the CMR [Confidential Morbidity Report form], there is a field that says pregnant, but it is often not filled out. If filling out this field were more enforceable, the work would be reduced.*

Recognizing that data about pregnancy continue to have high levels of missingness in lab reports despite the CCR changes, in August of 2021 the California Perinatal Hepatitis B Prevention Program of the California Department of Public Health released an updated Coordinator Handbook, which continued to specify: "Health department staff must review all reports of HBV-infected individuals to identify women who are of childbearing age (i.e., 14 to 45 yrs.) and then contact the physician's office to determine if any of these women are pregnant. If an HBsAg test is ordered as part of a prenatal panel from one of the major labs, specific CPT codes could be used to identify pregnant women."[36] However, no such program or guidance currently exists for perinatal HCV. It is also important to note that this strategy will miss people who could be pregnant but are not identified as "women" in the data.

RECOMMENDATION 4: **Provide reminders and follow-up communications to improve completeness of the pregnancy status field on lab reports submitted to SFDPH, as required by the California Code of Regulations since 2019. This will not only improve tracking of perinatal HCV, but perinatal HBV, congenital syphilis, and other reportable diseases with important implications for pregnancy outcomes.**

In lieu of excellent lab reporting, it is also possible to do proactive case reporting and panel management in the SFHN through Epic. This effort is already underway by Rachel Grinstein in the Community Health Equity & Promotion (CHEP) Branch of SFDPH, in coordination with Aminah Habib in Disease Prevention and Control (DPC). Rachel has built an HCV registry for the SFHN in Epic that can be run to pull a list of all active patients living with HCV, with a variety of other demographics or indicators. This registry is in the final stage of development, at which point it can be run within CHEP or DPC on a routine basis, but also be advertised to providers in the SFHN so they can run the query on their own patient panels. This registry does not currently pull pregnancy status, but this could be easily modified. Additionally, Angie Miller manages a pregnancy registry of every pregnant patient at ZSFG, which could be used to query whether HCV screening had been conducted on each patient. Rachel suggested that once up and running, she could run her SFHN-wide HCV registry query once a quarter, working especially to identify people living with HCV who are co-infected with HIV (via a regular match between this registry and eHARS via the HIV Surveillance Unit), pregnant, pediatric cases, and potentially people who have the capacity to become pregnant and do not have a medical home where they are regularly engaged in care. This list of patients with high priority for follow-up will then be passed to someone within DPC, who can contact providers to provide support for screening or treatment as appropriate, and reach out to the patient directly for navigation to care as needed. Alternatively, this workflow could be incorporated into upcoming expanded DIS programming, as cross-training across disease silos would be beneficial for the DIS trainees and SF residents alike.

RECOMMENDATION 5: **Systematize Data-to-Care procedures for people who are pregnant (or have the capacity to become pregnant, with notable risk factors for undiagnosed HCV infection) within the SFHN, using the Epic HCV case registry developed by Rachel Grinstein and/or the ZSFG pregnancy registry handled by Angie Miller. Once the query for this case registry has been fully built out, it should be regularly run within CHEP/DPC and also promoted to individual providers for panel management.**

Once pregnant people living with HCV have been identified through the various systems recommended above, SFDPH must have the capacity for timely follow up with patients through birth and up to three years post-birth, until infants that have developed chronic HCV infection can be safely treated and cured. There are four main ways this follow-up could be handled, which are not mutually exclusive:

1) **Create a perinatal HCV program modeled after the perinatal HBV program, currently coordinated by Ligia Afu-Li.** In this model, a key person within DPC would be responsible for receiving notification of potential perinatal cases of HCV, and would either follow up with providers to support *them* in providing appropriate care, or do direct patient outreach to support linkage to care. For this model to be effective, data quality would have to be improved in both lab reporting and the SFHN HCV case registry to ensure cases are being completely identified in a timely way. Notably, Aminah Habib's position within DPC was created through grant funding from CDC-RFA-PS21-2103, Integrated Viral Hepatitis Surveillance and Prevention Funding for Health Departments. This grant offers 5 years of funding for this position and provides an important opportunity for San Francisco to improve its response to perinatal HCV; however, the grant comes with other critical points of focus that will detract from Aminah's ability to focus on this issue specifically – which may be required, given the magnitude of effort required by Ligia for perinatal HBV.

2) **Establish a perinatal HCV specialist within the LINCS team, supported by the Perinatal Linkage Group in the SFHN.** This would be similar to how congenital syphilis is currently handled in San Francisco, with Alyson Decker a member of the LINCS team that focuses specifically on care to address and prevent congenital syphilis. San Francisco has a Congenital Syphilis Case Review Board, where the team debriefs each case of congenital syphilis, looking at bright spots, missed opportunities, and planned actions. To address the urgency of congenital syphilis – which is a preventable public health emergency with potentially severe implications for the health of the fetus – the SFDPH first activated to respond as a public health emergency, yet found that bringing people together around an important public health issue wasn't enough to make progress. Instead, systems changes were needed for providers and incentives for screening or follow-up care were required for movement to finally be made. During the COVID-19 pandemic, the congenital syphilis activation was discontinued in favor of completing an A3[1] in May 2021 for improvements in congenital syphilis response. This A3 led to creation of a Congenital Syphilis Prevention Task Force, which has worked (even during COVID-19) thanks to dedicated time of Alyson Decker to coordinate and lead this group. The Task Force also includes provider champions, including Dr. Nika Seidman at HIVE, who may also be a great resource for perinatal HCV. Since May 2021, the group has accomplished many things including adding a "Lost to follow-up, syphilis treatment needed" flag to Epic for anyone in the SFHN (including the ZSFG Emergency Department), and hosting a weekly call to discuss and troubleshoot outreach to anyone who is known to be pregnant with untreated syphilis and lost to follow-up. In short, Alyson's work, the congenital syphilis A3, and the work of both the Congenital Syphilis Case Review Board and the Congenital Syphilis Prevention Task Force can serve as models for a program to address and eliminate perinatal HCV in San Francisco.

RECOMMENDATION 6: **Convene a Perinatal HCV Task Force or discuss integration of perinatal HCV into the existing Congenital Syphilis Task Force. This group could then complete an A3 and – if determined by the Task Force to be the best option – systematize follow-up and linkage to care for pregnant people living with HCV through a dedicated LINCS position.**

3) **Leverage increasing funding for Disease Investigation Specialists to build DPC's capacity to investigate all acute cases of HCV and follow pregnant people living with HCV until babies can be determined to be HCV-negative or treated and cured.** One positive outcome of the COVID-19 pandemic has been the increased recognition of the importance of case investigation and contact tracing during an epidemic. DPC is responsible for case investigation and follow-up for all communicable diseases in San Francisco except HIV, TB, and STIs; however, disease investigation specialists (DIS) within DPC do fairly passive investigations, almost entirely by phone, with hardly any field work. (Case investigation and partner services for HIV and STIs is handled by City Clinic or LINCS and involves a lot of field work.) HCV is a challenging disease for case investigation in this context, as its primary modes of transmission are not sex-related like HIV and STIs; however, passive follow-up via phone is unlikely to be effective with the group at highest risk for HCV in San Francisco (especially people who inject drugs and/or are unhoused). With the influx of money to hire and train a large number of new DIS staff within DPC to boost capacity, this is an opportunity for SFDPH to also build capacity to conduct more active case investigations for perinatal HCV (and potentially

[1] An A3 is a tool commonly used within the *Lean Six Sigma* method of organizational quality improvement. It is a framework that helps to identify problems, develop solutions, track the impact of changes, and adjust as needed.

HBV). DIS within DPC could investigate all acute HCV cases reported to SFDPH, and follow all pregnant people diagnosed with HCV infection until birth, to support treatment of the parent and testing of the baby, helping to ensure treatment at 3 years old if indicated.

RECOMMENDATION 7: **Leverage incoming COVID and infectious disease funds for hiring and training new DIS staff within DPC to improve investigation of all acute HCV cases, and follow people who have HCV to ensure treatment after birth, and testing/treatment of the babies as appropriate.**

4) **Improve the use of eConsult for perinatal and pre-conception HCV screening and treatment.** In 2017, the primary care-based HCV treatment initiative team at SFHN established what was then known as "eReferral," a system to support primary care providers who had been trained to provide HCV treatment to their patients. When a provider in the SFHN has diagnosed someone with HCV and would like to treat them but is unsure what to do, they can place a request for a consult with a clinician who will help them determine the best next steps. Today, the system works generally the same, though with the SFHN conversion to Epic, the system was rebranded as eConsult. According to David English, an MD who answers eConsult requests for anyone with complex needs not easily handled by one of the pharmacists, in the area where you ask a question (e.g., indicate interest in providing HCV treatment) there is a link to a PDF summarizing the "policy" (e.g., treatment protocol) for that issue. Currently eConsult includes a single link for HCV treatment generally; Dr. English suggested that it might be helpful to have two links appear for someone searching for HCV – perinatal/pre-conception HCV treatment, and general adult HCV treatment. This would not only provide an opportunity for more detailed information about treatment considerations during or before pregnancy, but would also raise provider awareness more generally about perinatal HCV as a public health issue.

RECOMMENDATION 8: **Work with staff at UCSF to add a separate link for information and policies related to perinatal/pre-conception HCV care in eConsult, in addition to the general HCV treatment link that now exists.**

Theme 3: More can be done to retroactively identify undiagnosed pediatric cases of HCV

While the most effective and proactive strategy to address perinatal HCV would be to improve rates of screening, diagnosis, and engagement in care for people *while* they are pregnant, if those opportunities are missed, it is also valuable to identify undiagnosed pediatric cases. With minimal extra effort, it would be possible to check the registry of every person ever pregnant at ZSFG; those records could be cross-checked with HCV screening data to identify people who may have been pregnant and never screened for HCV, so they can be contacted and either the parent(s) or child can be tested if such testing seems warranted at this time. This would also allow SFDPH to look for patterns regarding who was not screened, to identify points of intervention (e.g., is it certain providers who routinely don't screen their patients? They could be contacted and supported to begin screening). Even more comprehensively, according to Amy Nishimura, once the registry match infrastructure and match programs have been developed it would take minimal effort for the Applied Research, Community Health Epidemiology, and Surveillance (ARCHES) Branch to maintain matching the chronic HCV registry with birth records from the Office of

Vital Records. This match would identify any people known to be living with HCV in San Francisco who have given birth, and identify them as candidates for follow-up. Per Amy there would likely be so few cases that administrative follow-up on cases matched between the registries could be handled by a 9924 or similar, referring any complex cases to DIS at DPC or LINCS.

RECOMMENDATION 9: **Implement a one-time match between the HCV case registry and San Francisco birth records. As the initial match is being planned and implemented, work with the Perinatal HCV (or Congenital Syphilis) Task Force to determine the best strategies for contacting matches for follow-up – in partnership with their OB/GYN or primary care providers if possible – and referring them for DIS services or linkage to care if appropriate. After the initial match is complete, explore implementation of a system for regular (at least annual) matching by ARCHES to identify subsequent cases where HCV infection is suspected with a person who was pregnant.**

Theme 4: More work can be done to identify and treat people living with HCV who have the capacity to become pregnant

Regardless of the important steps taken to identify pregnant people living with HCV and ensure they and their babies are eventually treated, the fact remains that the most effective way to prevent perinatal HCV infection is to identify and treat people living with HCV who have the capacity to become pregnant, *before* pregnancy occurs. According to the HCV case registry within ARCHES, 400-500 cases of HCV infection are reported each year among women of childbearing age, with approximately 200 of those being first-time case reports. However, the case registry is known to be an incomplete picture of the total number of HCV cases in San Francisco, as it requires a case to be both diagnosed and reported to the health department. As a point of comparison, *End Hep C SF* estimated a total of somewhere between 1,300 and 6,000 cisgender women of childbearing age likely living with untreated, chronic HCV infection in San Francisco in 2019; others who can become pregnant may not be captured by these data.

Multiple community-based organizations interviewed for this assessment (including San Francisco AIDS Foundation and HealthRIGHT 360, two major sources of community-based HCV testing in the city) said that increased HCV screening of people with the capacity to become pregnant was possible, should this be a strategy recommended by the health department. However, many noted that this strategy would only be worthwhile if people living with HCV who could become pregnant were able to quickly and easily access treatment, potentially with some sort of prioritization for services (especially if unhoused, etc.).

Ultimately, SFDPH will need to determine the priority given to increasing screening rates among the large number of people of childbearing age in San Francisco. One option is to educate community and medical providers about the importance of HCV screening for this population when specific risk factors for HCV infection are present (e.g., history of injection drug use, being homeless or marginally housed, having been incarcerated, etc.). This could be done through Health Advisories, primary care bulletins, and/or presentations where CMEs or CEUs are offered, to incentive providers to engage and learn – similar to strategies already used in Philadelphia, New York City, and the state of Kentucky.

It is important to underscore that any work done in this area will have to be done with sensitivity to issues of pregnancy. As Jessica Naugle noted:

One of the things we've learned in dealing with anything related to pregnancy is there is a lot of trauma associated with it. Always be mindful of potentially traumatic background. For example, child separation. You have to be careful about how to frame a campaign or a testing and treatment effort. Check in with people to see how messaging lands before launching the campaign. Any time you are bringing up pregnancy [in the context of HCV infection], make sure people understand this is something that is a lot heavier than it might be in another population. Light-hearted messages may not feel relatable. On the other hand, some people may be unrealistically hopeful about a pregnancy even after losing three other kids to the system.

Becca Schwarz from HIVE explained that it's important for providers to *ask* people whether they desire children. "At HIVE we learned that doctors would assume pregnancy was accidental, even when it was actually wanted – but people didn't feel they could say that, because of factors in their life including but not limited to HIV status," she said. When people are considering the possibility of becoming pregnant (whether intentionally or unintentionally), it can be an important time when they are open to making changes and improving their health. This makes the window of childbearing age a valuable time to have conversations about HCV screening and other health-promoting steps people can take *before* becoming pregnant.

RECOMMENDATION 10: **Develop an education campaign for community-based and clinic-based providers to emphasize the importance of HCV screening for people who could become pregnant, particularly if they have known risk factors for HCV infection. At a minimum, providers should be encouraged to *sensitively* ask people with the capacity to become pregnant who present for HCV testing about whether they are pregnant or plan to become pregnant, and to provide education and prevention messaging about HCV during pregnancy.**

Finally, in addition to using the Epic HCV registry built by Rachel Grinstein for identifying people living with HCV who are pregnant, this process could be expanded to allow for panel management of transgender/nonbinary patients and cisgender women who can become pregnant and have been diagnosed with HCV, so their providers can initiate treatment or refer them elsewhere for treatment before they (potentially) become pregnant. Identifying the patients who could become pregnant before their HCV is treated would be relatively easy and would require limited resources; however, following up with providers to encourage treatment initiation on such a large group of people would likely be time intensive. It would require resources beyond Aminah Habib's position in DPC, potentially including development of a system for notification of SFHN providers via Epic, and connection to eConsult (if needed) to support treatment.

Theme 5: There is an opportunity to encourage studies of HCV treatment for pregnant people

Various small sized studies in the United States and internationally have evaluated the pharmacokinetics of DAAs that have achieved SVR and cited no safety concerns.[37,38] However, before FDA approval is likely for DAAs for pregnant people, larger clinical trials will be necessary to evaluate the safety of DAAs in that population. According to interviews conducted for this assessment, treatment during pregnancy is being considered by some clinicians on an individual basis after a patient-physician discussion about the potential risks and benefits. However, more work will need to be done locally before stronger steps can be taken to treat people for their HCV infection while pregnant.

Within San Francisco, many patients living with HCV have their Medi-Cal or other health insurance through the San Francisco Health Plan (SFHP), the city's managed care plan. When providers wish to prescribe medication off-label (such as HCV treatment for a pregnant patient) they must request prior authorization through SFHP. According to Jessica Shost, a pharmacist with SFHP, prior authorization can generally be obtained for off-label treatment with at least two peer-reviewed studies demonstrating safety and effectiveness with people similar to the patient desiring treatment. In January 2021, the State of California implemented a Medi-Cal pharmacy benefit "carve out," transitioning all pharmacy services to fee-for-service and centralizing Medi-Cal pharmacy services under a single Pharmacy Benefits Manager, Magellan Rx. While it is possible that prior authorization procedures for HCV treatment will become more onerous or otherwise change as this process unfolds, early indications are that a similar requirement for two peer-reviewed studies demonstrating safety and effectiveness will also be used for prior authorization of off-label treatments by Magellan Rx. In that case, San Francisco's perinatal HCV efforts could benefit greatly from some locally conducted studies of the safety and efficacy of DAA treatment during pregnancy, something within the capacity of UCSF.

RECOMMENDATION 11: **Work with UCSF to develop opportunities to internally fund or otherwise incentivize further study of the safety and efficacy of existing HCV treatments for pregnant people, ultimately leading to peer-reviewed publication of findings and an expansion of the ability for providers to treat pregnant people living with HCV and potentially avert a pediatric HCV infection.**

Recommendations List

RECOMMENDATION 1: For San Francisco to cohesively address perinatal HCV (ideally alongside perinatal HBV, HIV, and congenital syphilis), SFDPH should employ a multifaceted appoach. Community providers who already do work related to HCV (or work with people at high risk for perinatal HCV infection) should be brought into conversations about the city's efforts to eliminate perinatal transmission of all these diseases.

RECOMMENDATION 2: Issue a Dear Colleague letter or Health Advisory reminding clinical providers in San Francisco (including at community-based organizations offering HCV testing) about the updated CDC HCV screening recommendations for pregnant people; take other concrete steps to increase provider education on this issue in collaboration with the SFHN Perinatal Linkage Group (e.g., a presentation at an upcoming quarterly provider gathering for primary care providers in the SFHN).

RECOMMENDATION 3: Add HCV to the routine screening labs for all pregnant people in the SFHN, including Zuckerberg San Francisco General Hospital; related, implement Epic EMR prompts to remind providers about guidelines for lifetime HCV screening, with extra emphasis on testing for people who are pregnant or pre-conception.

RECOMMENDATION 4: Provide reminders and follow-up communications to improve completeness of the pregnancy status field on lab reports submitted to SFDPH, as required by the California Code of Regulations since 2019. This will not only improve tracking of perinatal HCV, but perinatal HBV, congenital syphilis, and other reportable diseases with important implications for pregnancy outcomes.

RECOMMENDATION 5: Systematize Data-to-Care procedures for people who are pregnant (or have the capacity to become pregnant, with notable risk factors for undiagnosed HCV infection) within the SFHN, using the Epic HCV case registry developed by Rachel Grinstein and/or the ZSFG pregnancy registry handled by Angie Miller. Once the query for this case registry has been fully built out, it should be regularly run within CHEP/DPC and also promoted to individual providers for panel management.

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